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(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 624 383 A1**

(12) EUROPEAN PATENT APPLICATION

(21) Application number: 93830198.3

(51) Int. Cl.[5]: **A61N 1/00**

(22) Date of filing: **11.05.93**

(43) Date of publication of application:
17.11.94 Bulletin 94/46

(84) Designated Contracting States:
AT BE CH DE DK ES FR GB GR IE IT LI LU MC NL PT SE

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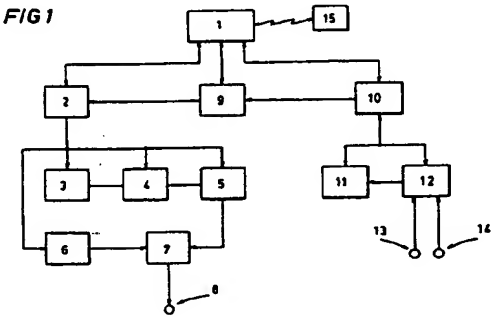
(54) A neural stimulator.

(57) A neural stimulator comprises two receiving and transmitting devices (15, 1), one located outside the body of a patient, the other implanted in the part of the body to be stimulated and associated with a first set of electrodes (8) through which signals generated by the implanted device (1) are passed into the surrounding tissue; also associated with the implanted device (1) are a second set of electrodes (13, 14) serving to monitor selected bioelectrical functions or activities of the body, and a group of components (10, 9, 2) capable of processing the signals sensed by the monitoring electrodes (13, 14), which therefore can be used as a feedback control in defining at least certain of the parameters of the stimulation signals emitted from the first electrodes (8).

FIG 1



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A feedback path is thus established between the information received from the electrodes 13 and 14 and processed by the circuits 11 and 12, and the stimulation signal circuits, effected by way of the interaction program 9 and therefore the stimulation program 2, in such a manner that the stimulation circuits can be piloted to alter the shape of the output signals as dictated by the algorithm entered in the program.

There now follow some examples of the application of a stimulation of this type.

In the case of treatment for angina pectoris, the onset of an ischaemic attack, inducing pain, will be reflected on the ECG by a low takeoff from the QRS complex; the stimulator must respond in such a way as to elevate the takeoff, ceasing stimulation once the correct waveshape has been restored.

In the case of stimulation for vascular diseases, the amplitude of certain premature waves in the ESP signals will vary significantly when the stimulus is effective: accordingly, the action can consist in maintaining the stimulation parameters at values tending to induce such a change in ESP waveshape, thereby obtaining an effective stimulation.

The need may arise in certain instances to measure the potentials evoked by stimulation in positions inaccessible to the implanted electrodes 13 and 14. In such instances, an external ESP recorder can be used, but with the averaging trigger obtained by way of the telemetering facility 1.

From the constructional standpoint, the stimulator (described thus far in purely operational terms) can be embodied from discrete circuit components such as will incorporate solutions of the various blocks mentioned in dedicated hardware.

In the example of fig 2, stimulation signals are generated by a microcontroller (or microprocesser) denoted 20; with such a component, the stimulator will be able to perform averaging functions on a numerically broad sample of received signals, as well as piloting the stimulation parameters using feedback control derived from evoked potentials.

Still with reference to fig 2, which illustrates a possible architecture for the system, 22 denotes a telemetering interface allowing the acquisition (via an electrical, electromagnetic or RF coupling) of data and commands from outside the body by way of a coder-decoder or codec 21 compatible with the external receiving and transmitting element 15. 23 denotes an erasable programmable read only memory containing at least one program utilizing commands received telemetrically by way of the interface 22; one such program contained in the EPROM 23 will serve to generate electrical signals, by way of the microcontroller 20, of which the polarity, frequency, duration and amplitude are selectable and determined by dedicated interfaces respectively denoted 26, 27, 28 and 29. The first such interface 26 pilots a selector 31 capable of reversing the polarity of the output signal to the electrodes 8, whilst the remaining interfaces 27, 28 and 29 serve to establish the waveshape and amplitude of the signal at the output of a driver denoted 30.

The EPROM 23 also receives and stores operating instructions for an analog-digital interface 25 in receipt of the signals sensed by the monitoring electrodes 13 and 14 and affording the following functions: the activation of averaging on input signals, selection of the number of values to be sampled, of the interval between one value and the next, and of the type of algorithm to be applied; also the inhibition or enabling of feedback control algorithms which utilize the parameters of evoked potentials, monitored by the electrodes 13 and 14 and amplified and filtered by a circuit denoted 32, to modify the stimulation parameters.

All parameters received telemetrically and creating the set-up configuration for the stimulator remain stored in a random access memory 24, which also holds the data acquired by the A/D interface 25. Accordingly, both the stimulation parameters and the acquired and processed monitoring data can be encoded by the codec 21 and transmitted outwards, away from the body of the patient.

Fig 3 shows a possible flow chart applicable in the case of the software for a solution as in fig 2. 41 denotes an initialization block which will come into operation at power-up, activating the various peripheral functions (timer, trasmit or receive data, etc.) and setting the default parameters for stimulation, for averaging and for evoked potential feedback control if selected, all of which can be altered thereafter by the user.

The blocks denoted 43 and 44 represent processes executed necessarily in real time, activated by a timed interrupt 42 and taking absolute priority: the timer will be set according to the frequency selected for activation of the A/D conversion and averaging processes, both of which are performed by the block denoted 44, and for generation of the stimuli by the block denoted 43. On receipt of an interrupt generated by the timer, the CPU assigns absolute precedence to these two processes.

The data needed for the averaging operation, if in use, is stored in a memory location afforded by the relative block 44 and then relayed to a diagnostics block 45 which will count the algorithms utilized in feedback control of the stimulation parameters. This function will be enabled or otherwise by the user externally.

During the interval between successive interrupts, the CPU will monitor a telemetering input/output interface 46, verifying whether or not

there is a current call for data, from a block denoted 48, or a code for a command, from a block denoted 47, to enter or alter stimulation parameters.

In the case of a call for data (evoked potentials, ECG, status of stimulation parameters) the relative block 48 will be enabled concurrently with transfer of the data to the encoding and telemetering system by way of the I/O interface 46.

As regards the entry or alteration of parameters, the new stimulation values (frequency, duration, amplitude, polarity) or the values governing the acquisition of external signals (number of signals to be averaged, type of signal, etc.) will be set by the relative block 47 as and when required.

Where operation in the interactive mode is enabled, the diagnostics block 45 will be programmed with the required type of algorithm and feedback control via the relative block 47 duly activated.

Claims

1. A neural stimulator, of the type comprising first receiving and transmitting means (15) located externally of the body of a patient, second receiving and transmitting means (1) located internally of the body of the patient substantially in contact with the tissues to be stimulated and affording a first plurality of electrodes (8) by which the tissues are invested with signals generated from the output of the second receiving and transmitting means (1), and means, associated with the second receiving and transmitting means (1), by which to monitor bioelectrical functions or activities, characterized
   - in that means by which to monitor bioelectrical functions or activities consist in a second plurality of electrodes (13, 14); and,
   - in that it comprises means (10, 9, 2) located internally of the body of the patient, associated with the second receiving and transmitting means, capable of processing the bioelectrically derived signals sensed by way of the monitoring means (13, 14) and determining at least certain parameters of the stimulation signals emitted from the first plurality of electrodes (8).

2. A neural stimulator as in claim 1, wherein means by which to monitor bioelectrical activities consist in electrodes (13, 14) capable of sensing evoked somatosensory potentials, associated with the second receiving and transmitting means (1) either directly or by way of the first receiving and transmitting means (15).

3. A neural stimulator as in claim 1, wherein means by which to monitor bioelectrical activities consist in electrodes (13, 14) capable of sensing electrocardiographic signals.

4. A neural stimulator as in claim 1, wherein means by which to monitor bioelectrical activities consist in electrodes (13, 14) capable of sensing evoked somatosensory potentials and electrocardiographic signals.

5. A neural stimulator as in claim 1, wherein the electrodes (13, 14) of the monitoring means are connected to the first plurality of electrodes (8) by way of processing means (10, 9, 2) comprising means (11, 12) by which to filter and amplify at least input signals.

6. A neural stimulator as in claim 5, wherein means by which to filter input signals comprise a processing element (11) capable of averaging the values of the signals received.

7. A neural stimulator as in claim 1, wherein signals emitted by the first plurality of electrodes (8) are generated by means comprising:
   - a microprocessor (20), connected to the output of a coder-decoder (21) in two-way communication with the first and second receiving and transmitting means (15, 1), the monitoring means (13, 14) and the electrodes (8);
   - dedicated circuits (26, 27, 28, 29) piloted by the microprocessor (20) and serving respectively to determine the polarity, frequency, duration and amplitude of the stimulation signals emitted by the electrodes (8);
   - at least two memory devices (23, 24) associated with the microprocessor (20), a first capable of storing at least a stimulation program defining the frequency, duration, amplitude and polarity of the stimulation signals emitted by the electrodes (8), and a second capable of storing data supplied by way of the monitoring means (13, 14), in such a manner that stimulation signals can be generated to parameters determined on the basis at least of the stimulation program and of the data supplied by way of the monitoring means (13, 14).

8. A neural stimulator as in claim 7, wherein the monitoring means (13, 14) are associated with the microprocessor (20) by way of an am-

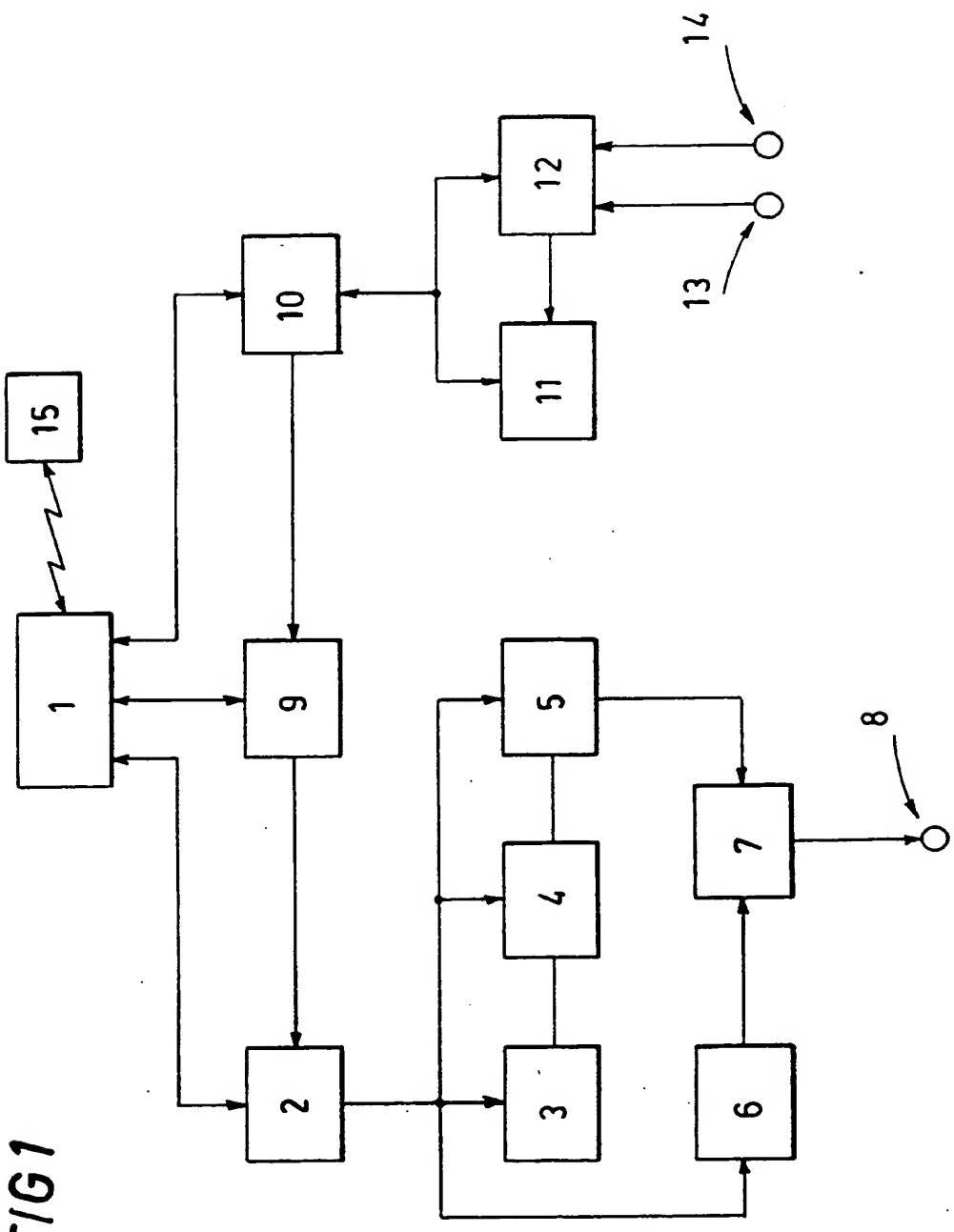

FIG1

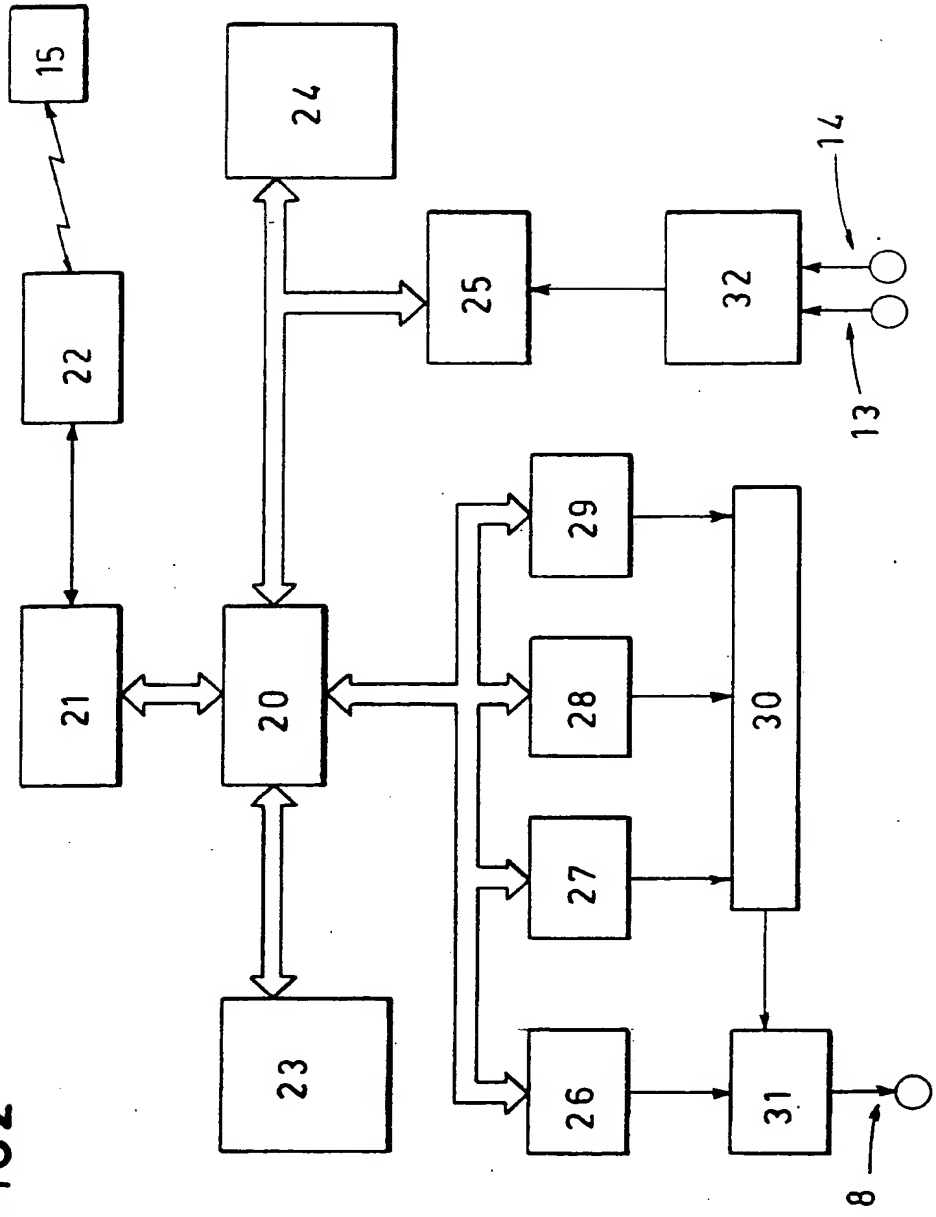

FIG2

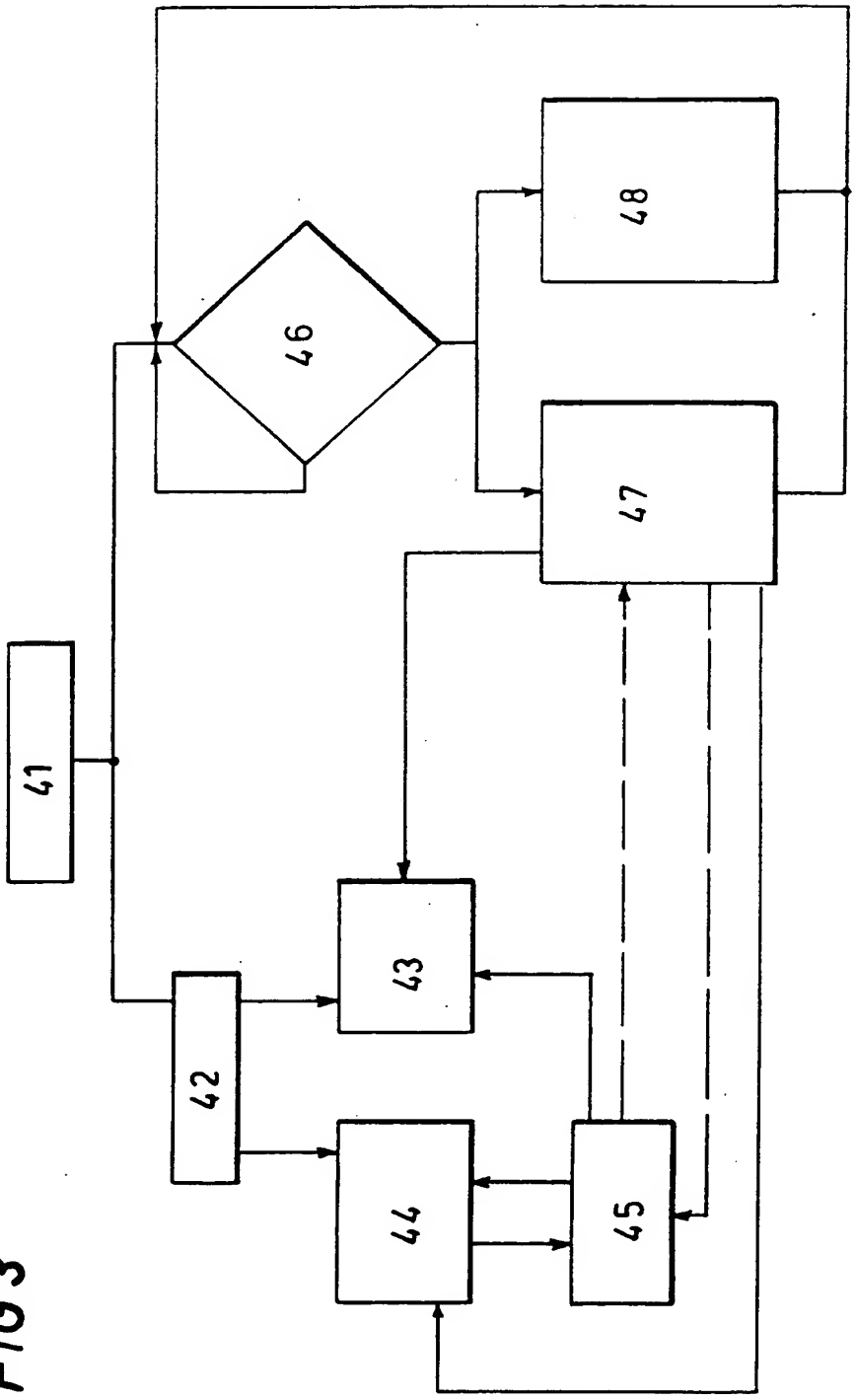

FIG 3

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 93 83 0198

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.5)
X	EP-A-0 392 800 (INTERMEDICS INC.) * the whole document * ---	1-10	A61N1/372 A61N1/34
X	WO-A-85 01213 (ZABARA) * page 8, line 24 - page 11, line 20 * ---	1-5	
A	US-A-5 058 584 (BOURGEOIS) * column 1, line 38 - column 4, line 8 * -----	1,2,5,7	

TECHNICAL FIELDS SEARCHED (Int.Cl.5)

A61N

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	18 October 1993	LEMERCIER, D

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